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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/043,366	01/10/2002	Iwao Katsuyama	KUP-D0135	6348

2292 7590 03/20/2003

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 03/20/2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/043,366

Applicant(s)

KATSUYAMA, IWAO

Examiner

Daniel M Sullivan

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 41, 42 and 44-72 is/are pending in the application.
- 4a) Of the above claim(s) 41 and 42 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 49-54, 62, 65 and 68 is/are allowed.
- 6) ☒ Claim(s) 44-48, 55-61, 63, 64, 66, 67 and 69-72 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 January 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This Non-Final Office Action is a response to the “Amendment under 35 U.S.C. § 1.111” filed 3 January 2003 (Paper No. 12) in reply to the Non-Final Office Action mailed 3 December 2002 (Paper No. 7). Claims 1-40 and 43 were considered in Paper No. 7. Claims 1-40 and 43 were canceled and claims 44-72 were added in Paper No. 12. Claims 41, 42 and 44-72 are pending in the application. Claims 44-72 are under consideration herein.

#### ***Drawings***

The formal drawing filed 3 January 2003 (Paper No. 10) are approved.

#### ***Response to Amendment***

Objection to and rejection of claims 1-40 and 43 is rendered moot by cancellation of the claims in Paper No. 12.

#### **Specification**

Objection to the abstract is withdrawn.

#### ***New Grounds for Rejection***

#### ***Claim Rejections - 35 USC § 112***

Claims 70-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of the claimed subject matter are unclear because the claimed methods do not clearly set forth how the terminal process step which relates back to the method described in the preamble. Amending the claims to conclude with a phrase such as “wherein said difference in osmotic pressure produces corneal epithelial damage” would obviate this rejection.

***Claim Rejections - 35 USC § 102***

Claims 44-48, 55-61 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Gilbard *et al.* (1984) *Ophthalmology* 91:1205-1212 (cited in Paper No. 7).

In response to the previous rejection of claims 1, 3, 5-8, 10 and 43 as anticipated by Gilbard *et al.*, Applicant has filed new claims 44-48 and 61 directed to an experimental animal having corneal epithelial damaged produced by contacting the cornea with a water-absorbing material wherein the water-absorbing material is limited to a polyol, an amino acid, a peptide and a water-soluble polymer, and argues that the claims are not anticipated because Gilbard *et al.* discloses a method wherein the water-absorbing material is a metal salt. This argument has been fully considered but is not found persuasive. Claims 44-48 and 61 are product-by-process claims and as such reads on an experimental animal having corneal epithelial damage made by any equivalent means. *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) states: “[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.”

Gilbard *et al.* teaches that results obtained using corneal explants *in vitro* are the same regardless of whether glucose or sodium chloride is used as the osmotic agent (paragraph bridging columns 1 and 2 on page 1208). Absent evidence to the contrary, the skilled artisan would understand that the experimental animal having corneal epithelial damage taught by Gilbard *et al.* would be the same as the instant claimed animal regardless of whether the osmotic agent used to produce the animal was glucose or metal salts because Gilbard demonstrates that the two osmotic agents are equivalent in the corneal epithelial damage they produce. Therefore, the experimental animal taught by Gilbard *et al.* anticipates the claims for the reasons set forth in the previous office action regarding anticipation of claims 1, 3, and 5-8.

Claims 55-60 and 63 are directed to experimental animals having corneal epithelial damage, wherein the epithelial damage is caused by contacting the ocular cornea with a water-absorbing material through a water-permeable membrane. The specification teaches, “[t]he use of said water-permeable or semi-permeable membrane or film is advantageous in that, after contacted with the corneal surface, the water-absorbing material can be easily removed therefrom by simply peeling off the water permeable or semi-permeable membrane or film from the corneal surface” and that it is preferable that the film “gives no substantial influence on the physical properties or functions of the water-absorbing material” (page 10, paragraph 2). Thus, the specification teaches that the animal produced by the method using a permeable membrane will not differ from an animal produced by direct application of the water absorbing material. Therefore, the animal produced according to the method Gilbard *et al.* anticipates claims 55-60 and 61 for the reasons set forth above regarding anticipation of product by process claims.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gilbard *et al.* (*supra*).

Claim 70 is directed to method of producing an experimental animal having corneal epithelial damage, wherein said experimental animal is a non-human mammal, comprising contacting the ocular cornea with at least one water absorbing material. Again, Applicant has limited the water-absorbing material to a polyol, an amino acid, a peptide and a water-soluble polymer and argues that Gilbard *et al.* does not suggest the instant method because Gilbard teaches the method wherein the water-absorbing material is a metal salt. However, given that Gilbard *et al.* teaches that the corneal epithelial damage produced in corneal explants by salt and glucose are equivalent, it would be *prima facie* obvious to one of ordinary skill in the art to substitute glucose for salt as the water-absorbing material in the method of Gilbard *et al.* As the identity of the water absorbing material is the only difference between the method of Gilbard *et al.* and the instant claimed method, the claimed invention as a whole would therefore have been obvious to one of ordinary skill in the art at the time the instant invention was made.

Claims 64, 66, 67 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yerxa *et al.* (1999; U.S. Patent No. 5,900,407) in view of Gilbard (1984; *supra*) and in further view of Fujihara *J. Ocular Pharm.* (1995) 11:503-508 (cited in the previous Office Action).

Art Unit: 1636

As pointed out by Applicant, claim 64 corresponds to the canceled claim 27 and claim 67 correspond to the canceled claim 38 but are limited to a method of using the experimental animal of claim 44. Claims 66 and 69 correspond to the method of claims 64 and 67, respectively, limited to a method of using the experimental animal of claim 55. Again applicant argues that the claims are distinguished from the prior art in being limited to a method of using an animal wherein corneal epithelial damage is produced using a water absorbing material limited to a polyol, an amino acid, a peptide and a water-soluble polymer. Applicant argues that the secondary reference, Gilbard *et al.*, does not suggest the instant method because Gilbard *et al.* teaches a method wherein the water-absorbing material is a metal salt. However, for reasons set forth above, the experimental animal taught by Gilbard *et al.* is the same as the animal used in the instant claimed methods. Therefore, claims 64 and 67 are unpatentable over Yerxa *et al.* in view of Gilbard *et al.* and in further view of Fujihara for the reasons set forth in the previous office action regarding claims 27 and 38. Likewise, because the animal of claim 55 is the same as the animal taught by Gilbard *et al.* (*Id.*) claims 66 and 69 are also unpatentable over Yerxa *et al.* in view of Gilbard *et al.* and in further view of Fujihara for the reasons set forth regarding claims 64 and 67.

Applicant further argues that even if a *prima facie* case of obviousness has been made against the claims, the claims would still be patentable because of the unexpected superior effects of the instant disclosed invention. This argument is based on statements from the specification which indicate that the disclosed animal model is superior to models wherein the corneal epithelial damage is produced by simply drying the cornea. Applicant argues, “the present invention unexpectedly allows those skilled in the art to correctly evaluate the

Art Unit: 1636

therapeutic effects of medicine, to prepare an animal model in a shortened period...and to prepare an animal model having a pre-selected size of corneal damage". These arguments have been fully considered but are not found persuasive. First, because the animal model taught by Gilbard *et al.* is the same as the instant animal model, the features that allow the skilled artisan to evaluate therapeutic effects of medicine are inherent to the model. Next, because the claims are in no way limited to preparing an animal in about 60 minutes, this result is not relevant to the claimed subject matter. Finally, the rejected claims do not comprise limitations which would allow one to prepare an animal having a pre-selected size of corneal damage (i.e., a water impermeable membrane with a hole) and therefore, do not have this advantage.

Therefore, for reasons set forth in the rejection of claims 27 and 38 under 35 U.S.C. § 103(a) and herein above; claims 64, 66, 67 and 69 are unpatentable over the art of record.

#### ***Allowable Subject Matter***

Claims 49-54, 62, 65 and 68 are allowed.

The art of record does not teach, nor does it suggest a method of making an animal having corneal epithelial damage comprising contacting the ocular cornea with a water-absorbing material through a hole in a water impermeable membrane or an animal made by the method, which would comprise corneal epithelial damage limited to a defined region of the ocular cornea.

#### ***Conclusion***



Art Unit: 1636

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448.

The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms  
March 12, 2003

*Anne-Marie Falk*  
ANNE-MARIE FALK, PH.D  
PRIMARY EXAMINER